

## UNITED STATES PATENT AND TRADEMARK OFFICE

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| PPLICATION NO.     | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--------------------|--------------------|----------------------|-------------------------|------------------|
| 09/848,834         | 05/04/2001         | Stephen Grimes       | 1102865-0047            | 7489             |
| 7470               | 7590 05/21/2002    |                      |                         |                  |
| WHITE & CASE LLP   |                    |                      | EXAMINER                |                  |
|                    | JE OF THE AMERICAS |                      | HUYNH, PHUONG N         |                  |
| NEW YORK, NY 10036 |                    |                      | ART UNIT                | PAPER NUMBER     |
|                    |                    |                      | 1644                    | C                |
|                    |                    |                      | DATE MAILED: 05/21/2002 | φ                |

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

|   | Application No.         | Applicant(s)  |  |  |  |  |
|---|-------------------------|---|--|--|--|--|
| <b>V</b> .  |                         |   |  |  |  |  |
| Office Action Summany   | 09/848,834              | GRIMES ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner                | Art Unit  |  |  |  |  |
|   | " Neon" Phuong Huynh    | orrespondence address   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                         |   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |                         |   |  |  |  |  |
| 1) Responsive to communication(s) filed on  | _·                      |   |  |  |  |  |
| 24,   | action is non-final.    |   |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |                         |   |  |  |  |  |
| 4) Claim(s) 1-16 is/are pending in the application.   |                         |   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                         |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                         |   |  |  |  |  |
| 6) Claim(s) is/are rejected.  |                         |   |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                         |   |  |  |  |  |
| 8) Claim(s) 1-16 are subject to restriction and/or election requirement.  |                         |   |  |  |  |  |
| Application Papers  |                         |   |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |                         |   |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |                         |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                         |   |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  |                         |   |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                         |   |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |                         |   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                         |   |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                         |   |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |                         |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                         |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                         |   |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |                         |   |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                         |   |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                         |   |  |  |  |  |
| Attachment(s)   |                         |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal F | r (PTO-413) Paper No(s)<br>Patent Application (PTO-152)<br>heet . |  |  |  |  |

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Art Unit: 1644

## **DETAILED ACTION**

- The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- 2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3. Claims 1-16 are pending.

## Election/Restrictions

- 4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 8-12 and 15-16, drawn to a synthetic immunogen for inducing specific antibody against GnRH comprising a fusion peptide comprising a promiscuous helper T cell peptide epitope and immunomimic peptide, and a pharmaceutical injectable composition, classified in Class 424, subclass 192.1.
  - II. Claims 7 and 13, drawn to a method of inducing immune response against GnRH in an animal, classified in Class 424, subclass 192.1, and Class 424, subclass 811.
  - III. Claim 14, drawn to a method of producing an anti-GnRH immune response-inducing fusion peptide immunogen comprising preparing a chimeric peptide, classified in Class 435, subclass 69.7.

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The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups (II-III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the synthetic fusion peptide can be use for a different process such as binding assay. Therefore, they are patentably distinct.

Inventions of Groups II-III are unrelated. In the instant case, the method of inducing immune response versus the method of preparing a fusion peptide which require different ingredients such as the ones recited in claims 10-12 differ with respect to process steps and endpoints. Therefore, they are patentably distinct.

- 5. Because these inventions are distinct for the reasons given above and the searches are not coextensive, restriction for examination purposes as indicated is proper.
- 6. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:
  - If Group I, II or III is elected, the Applicant is required to elect a specific synthetic immunogen comprising a specific fusion peptide, a specific helper T cell peptide epitope, a specific immunomimic peptide epitope or analog thereof such as the ones recited in claim 11, and a specific spacer peptide such as the ones recited in claim 10. These fusion peptides, T cell epitopes from different species, immunomimic peptide epitope or analog thereof and linker differ with respect to their structures and biochemical properties. Therefore, they are patentably distinct.
- 7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7 and 14 are generic.
- 8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to 9. additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

- Should applicant traverse on the ground that the species are not patentably distinct, applicant 10. should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
- Due to the complexity of the claimed invention an oral restriction was not made. 11.
- Applicant is advised that the response to this requirement to be complete must include an election 12. of the invention to be examined even though the requirement be traversed.
- Any inquiry concerning this communication or earlier communications from the examiner should 13. be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
- Papers related to this application may be submitted to Technology Center 1600 by facsimile 14. transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

May 20, 2002

SUPERVISORY PATENT EXAMINER

**TECHNOLOGY CENTER 1600**